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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,744	08/18/2000	Brian F. Tack	IOWA:026US	7819

7590 07/29/2002
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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/29/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,744

Applicant(s) *File copy*

TACK ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 4-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election without traverse of 4/23/2002 in Paper No. 15 is acknowledged.

Applicants elected group I, claims 1 and 3 which are drawn to isolated antimicrobial polypeptides.

Claims 2, 4-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

2. Claims 1-31 are pending.

3. Claims 1 and 3 are under consideration.

Information Disclosure Statement

4. Applicants Information Disclosure Statement, received 6/25/2001, paper number 13 is acknowledged.

5. The listing of references in the specification (pages 99-104) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

6. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached from PTO 948.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting improper Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “selected from the group comprising of A, B, and/or C.” See *ex parte Markush*, 1925 C.d. 126 (Comm’r Pat. 1925).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahoney et al. (FEBS Letters, Vol.377, pp. 519-522, 1995) prior art already made of record in applicants’ 1449.

Claims 1 and 3 are drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Mahoney et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 2 and attached sequence alignments Accession numbers S68411 and S68412). Mahoney et al. also teach sterile water as pharmaceutically acceptable carrier (see material and methods). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bagella et al. (FEBS Letters, Vol.376, pp. 225-228, 1995) prior art already made of record in applicants' 1449.

Claim 1 is drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Bagella et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 1, section B and attached sequence alignment Accession number S68228). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or

Art Unit: 1645

unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Merluzzi et al. (Peptides, Vol.261, pp. 639-640, 1996) prior art already made of record in applicants' 1449.

Claims 1 and 3 are drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Merluzzi et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see page 639). Merluzzi et al. also teach water as pharmaceutically acceptable carrier (see page 640). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 1645

Tossi et al. (FEBS Letters Vol. 339, pp108-112, 1994).

Turner et al. (Antimicrobial and Chemotherapy Vol. 42, NO.9, pp.2206-2214, 1998).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnian-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnian-Shah, B.S. Pharm, M.S.

Biotechnology Patent Examiner

Art Unit 1645

July 26, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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